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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,253	11/04/2003	Pat D. O'Donnell	42581-P002P1	6108

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EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	**PAPER NUMBER**
3735	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,253	O'DONNELL, PAT D.	
	Examiner	Art Unit	
	CHRISTINE D. HOPKINS	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *9-17 and 20-21* is/are withdrawn from consideration.

5)☒ Claim(s) *4,18,19* is/are allowed.

6)☒ Claim(s) *1-3 and 6-8* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 8 December 2009. Claims 1-21 are now pending. The Examiner acknowledges the amendments to claims 3 and 4.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Staskin et al. (U.S. Pub. No. 2003/0045774). Staskin et al. (hereinafter Staskin) disclose surgical instruments and methods for introducing a sling into a patient suffering from urinary incontinence. Regarding claim 1, Staskin teaches a sling capable of being applied to an area beneath and supporting the urethra or bladder neck [0118]. A "tissue remodeling portion" is attached to and surrounding a section of the sling [0117]. The "tissue remodeling portion" is interpreted as the sheath of Staskin since its purpose, as that of the instant application, is to provide strength and structural reinforcement to the sling [0117]. The sling supporting the urethra may be composed of a surgical mesh [0026]. Referring to Fig. 4, a sling transfer instrument defines a curved shaft portion **60** between distal and proximal ends, with an attached insertion handle **64** at the proximal

end and at the distal end, a dilator **54** for attaching the sling to the distal end of the shaft [0115].

With reference to claim 3, the polypropylene mesh, as taught by Staskin, contains filaments of woven material, each having a thickness of approximately .024 inches [0120].

With reference to claim 6, Staskin teaches that the shaft portion, or needle **60**, has a diameter of approximately 3.175 mm, or "approximately" 3.5 mm and less than 5.1 cm. Since the instant application provides no reason for a diameter of about 3.5 mm to about 4.0 mm, the dimensions of the needle as disclosed by Staskin are capable of transferring a sling to an implant site.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin in view of Inman et al. (U.S. Pub. No. 2003/0065246). Staskin discloses the invention as claimed, see rejection supra; however Staskin fails to disclose specific dimensions of the indentations on the transfer handle for accommodating the fingers of a surgeon. Inman et al. (hereinafter Inman) disclose an instrument for introducing a

sling into the pelvic area of a patient suffering from urinary incontinence. Regarding claim 2, Inman teaches a handle **12** having a "digit control accommodation," or channel **32** (see Figs. 2 and 3). The height of the handle is preferably between 3.25 in. to 4.75 in. [0046] whereby the width is preferably one-third of the height [0053]. Since the channel extends the width of the handle, the width of the "digit control accommodation" or channel **32** is approximately 1.08 in. to approximately 1.58 inches, thus falling within the range specified in claim 2. Furthermore, the length of the channel is approximately 1 in. [0051], and its depth is approximately one-half of the width [0053], thus the width, if it was 1.2 in, would bring the depth of the "digit control accommodation" to 0.6 in., or 1.5 cm in accordance with claim 2. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have fit a sling transfer instrument such as that disclosed by Staskin, to have the dimensions of the digit control accommodation as proposed by Inman, in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure.

Regarding claim 8, Staskin discloses the invention as claimed, see rejection supra; however Staskin fails to disclose a transfer shaft for a sling having a luminous coating. Inman teaches a rod **14** of a transfer instrument (see Fig. 3) having a reflective coating for aiding visibility for the surgeon [0058]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have coated a transfer shaft, or needle, similar to that taught by Staskin, with a reflective or luminous material as suggested by Inman such that the instrument is easily viewed by the surgeon during application of a urinary incontinence sling within a patient.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (U.S. Pub. No. 2003/0045774). Regarding claim 7, Staskin discloses that the distal end of the shaft, or needle **60**, is oriented in a direction opposite of the curved portion (see Fig. 4). Furthermore, the distal end of the shaft portion is 1.0 cm, in length, since any length that is towards the distal end could be construed as "the distal end"; however Staskin does not disclose expressly that the progressively curved shaft portion is approximately 4.0 mm in width. Instead, Staskin indicates that the width is approximately 3.175 mm in order to facilitate passage through various tissues and reduce tissue trauma in transvaginal deployment [0177]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use construct the shaft portion to be approximately 4.0 mm in width because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Staskin's shaft portion and applicant's invention, to perform equally well with either the width taught by Staskin or the claimed approximate 4.0 mm width because both would perform the same function of facilitating controlled passage during transvaginal deployment. Therefore, at the time of the invention it would have been prima facie obvious to modify Staskin to obtain the invention as specified in claim 7 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Staskin.

Allowable Subject Matter

7. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 5, while the prior art teaches a surgical instrument for treating female urinary incontinence comprising a sling and sling transfer instrument, the prior art of record does not teach or fairly suggest a surgical instrument as claimed by Applicant, wherein the mesh section is approximately 60 cm in length, approximately 1.5 cm. to 3.0 cm at its widest and generally center-most position, and approximately 1.0 cm wide at each of its opposite ends.

8. Claims 4, 18 and 19 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 4, the prior art of record does not teach or fairly suggest a surgical instrument for treating incontinence as disclosed by Applicant, wherein a mesh section of a sling is comprised of absorbable polymers, and filaments of the section have a diameter of approximately .012 inch to 0.1 inch.

Regarding claims 18 and 19, the prior art of record does not teach or fairly suggest a suprapubic method for treating incontinence as claimed by Applicant, wherein the insertion handle of a first sling transfer instrument is used to guide a curved tip at the instruments distal end through the abdominal wall and retropubic space and further allowing the tip to be in contact with the posterior surface of the pubic bone as it traverses the retropubic space.

Response to Arguments

9. Applicant's arguments filed 8 December 2009 with respect to the objection to claims 3 and 4 have been fully considered and are persuasive. The objection to claims 3 and 4 has been withdrawn.

10. Applicant's arguments filed 8 December 2009 with respect to the rejection of claims 3, 4, 18 and 19 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 3, 4, 18 and 19 under 35 U.S.C. 112, second paragraph, has been withdrawn.

11. Applicant's arguments filed 8 December 2009 with respect to the rejection of claims 1, 3 and 6 under 35 U.S.C. 102(e) citing Staskin (U.S. Pub. No. 2003/0045774) have been fully considered and are not persuasive. Regarding claim 1, Applicant contends that Staskin does not teach "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder. However, this argument is not persuasive. The sling of Staskin is considered to be "contoured" by virtue of its ability to shape to a urethra (Fig. 7). Furthermore, according to its definition, "contoured" defines something which is molded or shaped to fit a particular contour or form. Even though the sling of Staskin is referred to as "tape" sling, it is held that the tape of Staskin is "shaped" to fit and support the urethra or bladder as noted in [0026] and [0116]. Furthermore, Staskin notes at [0118] and [0119] that alternative lengths, widths and thicknesses of the sling can also be used, including a wide variety of shapes, sizes, materials and treatments dependent upon the structure being supported,

thus further providing that the sling of Staskin is also capable of being contoured to "the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder." Therefore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant further contends, regarding claim 1, that the radius of the curvature of the needle **60** of Staskin is substantially constant and hence it is not "progressively curved" as required by the claim. However, this argument is not persuasive. It is held that Fig. 4 shows a "progressively curved" needle, and paragraph [0176] describes the needle as "generally curved and arcuate. Since it is curved over a length of the needle, it is deemed to be "progressively curved" in accordance with claim 1.

Regarding claim 6, Applicant contends that Staskin does not teach that the needle **60** has a diameter of approximately 3.5 mm to 4.0 mm. However, this argument is not persuasive. Staskin discloses that the diameter of the needle is approximately 3.175 mm, and therefore the term anticipates claim 6 which incorporates an "approximate" diameter of 3.5 mm. A definition of the term "approximate" is "near" or "to estimate." Therefore, the needle of Staskin is found to anticipate the language of claim 6. Applicant further contends that the needle of Staskin does not have a progressive curve with a "maximum radius of approximately 5.1 cm." However, this argument is not persuasive as any needle having a radius under 5.1 cm would

anticipate the claim. In view of the foregoing, the rejection of claims 1, 3, and 6 under 35 U.S.C. 102(e) citing Staskin (U.S. Pub. No. 2003/0045774) has been maintained.

12. Applicant's arguments filed 8 December 2009 with respect to the rejection of claim 7 under 35 U.S.C. 103(a) citing Staskin (U.S. Pub. No. 2003/0045774) have been fully considered and are not persuasive. Applicant contends that the distal end of the sling transfer instrument of Staskin is not oriented in a direction opposite that of the curved shaft portion in accordance with claim 7. However, this argument is not persuasive. Since the needle is curved, and the "distal end" is broad and doesn't define a definite structure, the "distal end" may also comprise a portion of the curve of the needle which may point in a direction opposite that of a different portion of the curved needle. A line drawn through any particular point of the needle will point in a direction different than that of a line drawn through another point of the needle given its curved nature. Applicant further contends that the distal end of the curved shaft portion of Staskin is not approximately 1.0 cm in length and 4.0 mm in width. However, this argument is not persuasive. "The distal end" of the needle could conceivably constitute any length. And as previously indicated in the rejection and response above, the width of the needle is "approximately" 4 mm [0177]. The length of Staskin would have been expected to perform equally as well, as the instant claim states an "approximate" number and both the procedures of the instant application and the prior art to Staskin are directed towards implanting a sling via a transvaginal method. In view of the

foregoing, the rejection of claim 7 under 35 U.S.C. 103(a) citing Staskin (U.S. Pub. No. 2003/0045774) has been maintained.

13. Applicant's arguments filed 8 December 2009 with respect to the rejection of claims 2 and 8 under 35 U.S.C. 103(a) citing Staskin (U.S. Pub. No. 2003/0045774) in view of Inman (U.S. Pub. No. 2003/0065246) have been fully considered and are not persuasive. Applicant contends that Inman does not teach a digit control accommodation on the insertion handle. However, this argument is not persuasive. The channel **32** is interpreted as the "digit control accommodation" as it provides for a space to accommodate a finger of a surgeon. The channel provides a surface on the handle which may be used to control movement of the handle by the surgeon (Figs. 2-4). Applicant further contends that Staskin does not teach a digit control accommodation dimensioned approximately 2.5 to 4.5 cm in length, 1.0 to 4.0 cm in width and 1.5 cm in depth. However, this argument is not persuasive. Staskin teaches a length of 2.54 cm, a width of 2.8 to 4 cm, and depth (being one-half the width) of 1.4 to 2 cm, thus covering the ranges presented in claim 2. The relevant paragraphs of Inman are found at [0046]-[0048] and [0051]-[0053]. Applicant also contends that there is no language in Inman that the tactile surfaces are used to control movement of the handle. However, this argument is not persuasive as such surfaces aid in securing the handle to the surgeon's finger/hand for controlled movement. In view of the foregoing, the rejection of claims 2 and 8 under 35 U.S.C. 103(a) citing Staskin (U.S. Pub. No. 2003/0045774) in view of Inman (U.S. Pub. No. 2003/0065246) has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
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